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| 09/706,778 | 11/07/2000 | Daniel Bichon | 1201-83 | 6925 |

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,778

Applicant(s)

BICHON ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-50 is/are pending in the application.
- 4a) Of the above claim(s) 3-31, 37, 38 and 45-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32, 33, 35, 36 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3-31, 37, 38 and 45-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 07/695,343.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on August 13, 2002 (hereinafter "the Amendment") has been entered. Claims 3-33, 35-50 are now pending. Claims 3-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.7. Claims 37-38, 45-50 are further withdrawn as they are directed to the non-elected species. Claims 32-36, 39-44 are under consideration.
2. This application contains claims 3-31, 37-38, 45-50 are drawn to an invention nonelected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

3. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 42-44 and all dependent claims thereof stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 and 43 respectively contain the broad recitation phospholipids and polyalkylene glycols, and "lecithins" and "polyethylene glycol" which is the narrower statement of the range/limitation. Amendment contains arguments that there are not

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such limitations within claims 42-43. *Amendment*, p. 6. However, claim 42 and 43 depend on claim 41 thus all limitation of claim 41 is incorporated into claims 42-43. Claim 41 recite "phospholipid like the lechithins" and claim 43, recite "poly alkylene glycols like polyethylene glycol and polypropylene glycol." Therefore, each rejected claim contains a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) and that is considered indefinite. See *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989).

Claim 44 stand rejected as it contains the trademark/trade name "freon." Arguments set forth in the Amendment are on the basis that the term "freon" is not indefinite, as recognized by ordinary artisans in the art such as Richard Chambers (attached Exhibition 1 to the Amendment), and that the USPTO has long acknowledged that the use of the term "freon" is acceptable in a claim language, and that the use of generic term in claims are permissible. *Amendment*, p. 6-8.

In response, Examiner states that pursuant to the 35 USC 112 2nd para., to determine whether the claim language is definite one must examine the claims to see whether the metes and bounds of the present invention can be adequately determined from the claim language. In the instant case, the scope of the claim is uncertain with respect to the compounds that can fall within the definition of the term "freon."

In the instant case, the scope of the definition for the term "freon" is changeable with time and has been modified since 1960s. Moreover, the definition includes numerous divergent meanings. On the one hand, the claim language may be very narrowly construed to a particular gaseous substance such as CF₄ as set forth by the

Declaration of Richard Chambers and the Dupont Bulletin. On the other hand the claim language might be asserted to broadly encompass all fluoro, bromo, chloro hydrocarbon compounds. There is nothing in the record to indicate that scope of such materials marketed under the trademark "freon." In addition, it seems evident that different manufacturers produce various materials, which contain perflourinated gases or compounds either alone or in combination with each other or other additives within the definition of "freon." Therefore, the scope of the term is not solely dependent on the nature of the hydrocarbon molecular structure rather the trademarked product.

Furthermore, the underlying question here is which fluorocarbon or "freon" must be employed in the claimed composition before infringement occurs. A patent applicant has an obligation that is imposed by 35 U.S.C. 112, second paragraph, to employ claim terminology which is definitive of what the public is not free to use. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). However, the use of a trademark in the manner employed by the instant claims resulted in claims, which fail to meet such obligation.

Further, the use of the term "freon" in other patents are not controlling in the prosecution of this application. Applicants are reminded that "Patents" are governmental grants of intellectual property rights. Accordingly, they are not legal precedent, nor are they law of the land. Therefore, previous use of the term "freon" in previous patents has no bearing in the prosecution of the instant claims. Subsequently, the rejection is proper for the reasons of record.

Doubl Patenting

5. Claims 32-36, 39-44 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,333,021; claims 1-22 of US Patent 6,200,548; claims 1-24 of US Patent 6,136,293; claims 1-17 of US Patent 6,123,922; claims 1-50 of US Patent 6,110,443; claims 1-13 of US Patent 5,840,275; claims 1-16 of US Patent 5,658,551; claims 1-19 of US Patent 5,271,928.

Examiner noted Applicant's desire to hold this rejection in abeyance until pending claims have been allowed.

Claim Rejections - 35 USC § 103

6. Claims 32-33, 35-36, 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Feinstein US Patent 4,774,958 or Temple US Patent 4,089,800 in view of Ganguly et al (J. Microencapsulation, 1989, 6:2:193-198).

Claims 32-33, 35-36, 39-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Feinstein US Patent 4,774,958 or Temple US Patent 4,089,800 in view of Ganguly et al (J. Microencapsulation, 1989, 6:2:193-198) as applied to claims 32-36 above, and further in view of Tickner US Patent 4,265,251.

Claims 32-33, 35-36, 39-44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhardt et al US Patent 5,425,366 in view of Ganguly et al (J. Microencapsulation, 1989, 6:2:193-198) and Tickner US Patent 4,265,251.

Applicant's arguments set forth in the Amendment, filed on August 13, 2002 have been fully considered but they are not persuasive. The arguments set forth in the Amendment are based on the following reasoning:

- There is no motivation in the art to combine the cited references. *Amendment*, p. 10-13.
- The references are not directed to the same field of endeavor. *Amendment*, p. 13.
- Each reference introduces teachings away from the instant claims. *Amendment*, p. 14-16.
- There is no reasonable expectation of success in combining the teachings of cited references and that Examiner employed improper hindsight to reconstruct the claimed invention. *Amendment*, p. 17-18.

First, Examiner replies that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *Id.* In the instant case, all elements of the cited references are taught in the combined teachings of the cited references for the reasons of record.

Amendment also argues that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the general knowledge in the art is clearly set forth by the teachings of Ganguly. Therefore, even assuming *arguendo* that motivation for creating the claimed porosity characteristics is not expressly described within the cited references, it is clearly provided by the knowledge generally available to one of ordinary skill in the art, because as taught by Ganguly modifying porosity and wall thickness is a function of polymeric concentration and the solvent used.

Amendment then enumerates deficiencies within each cited reference. Specifically, Amendment hints that there is no teaching or suggestion anywhere of dry microballoon that is able to form microballoon when dispersed in an aqueous carrier. Contrary to such arguments, the combined teachings of the references are also directed to such limitations. Temple clearly teaches dried microcapsules as the end products (see col 11, lines 13-16). Feinstein teaches aqueous solution of his denature polymeric shells (col 4, lines 44-54). Reinhardt teaches that his suspension is divided into 10 ml portions and freeze-dried to form lyophilizate that can be resuspended with water for injection purposes (see col 7, lines 51-63; examples 10, 36-39). Reinhardt's

freeze dried microballoons are within the meaning of the instantly claimed dried microballoons. Further, Tickner is solely used to teach the use of freon as a suitable gas, therefore, the combined teachings of the cited references meet the limitations of the instant claims.

The Amendment further traverses that modifications of the primary reference cannot change the principle of the operation of the primary reference. Amendment sets forth that for example Feinstein and Tickner can not be combined because Feinstein explicitly relies on the benefits of an albumin shell surrounding the gas while Tickner relies on the benefits of a free gas microbubble. *Amendment*, p. 16. Contrary to such argument, Examiner states that the combined teachings of the references do not lead to the level of modification that makes the primary references inoperable.

Moreover, Examiner states that again Tickner teaches suitable gases for ultrasound imaging include air, nitrogen, carbon dioxide and freon, so long as it is used in an amount that would not be harmful (see col 6, lines 65-68). Feinstein acknowledges such teachings and further employs air as his gas. (col 7, lines 11-18, and 36-50). Therefore, combining such teachings and modifying Feinstein's microbubbles to contain any gas enumerated by Tickner would have been an obvious modification, as recognized by both cited references. Using one gas for another does not lead to inoperability of microbubbles taught in Feinstein or Temple.

In response to applicant's argument that the cited references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the

applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all cited references teach methods of formulating and using various types of microvesicles. Accordingly, they are reasonably pertinent to the particular problem within the in vivo delivery of such products and may be properly be relied upon.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, all cited references are within the same field of endeavor and thus, they are combinable. Therefore, combining their respective teachings were within the level of ordinary skill in the art at the time of invention and the conclusion of obviousness based on their teachings is not improper hindsight, rather *prima facie* obviousness. Accordingly, claims stand rejected for the reasons for record.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
November 2, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200